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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,399	01/21/2002	Peter Michael Aljoscha Nern	DYOU13.1A2CP1	8256

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,399	NERN ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 17-19, 64, 65, drawn to nucleic acids, classified in class 536, subclass 23.1.

II. Claims 5-10, 55-57, drawn to methods of gene therapy, classified in class 514, subclass 44.

III. Claims 11-16, drawn to drug screening assays, classified in class 436, subclass 501.

IV. Claims 20-24, 46-50, drawn to a protein sequence, classified in class 530, subclass 350.

V. Claims 25-36, 58-63, drawn to methods of protein therapy, classified in class 514, subclass 2.

VI. Claims 37-45, drawn to protein drug screening assays, classified in class 435, subclass 7.1.

VII. Claims 51 and 52, drawn to agents, classified in class 514, subclass 1.

VIII. Claims 53 and 54, drawn to methods of using agents, classified in class 424, subclass 9.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions in Groups I-III, in Groups IV-VI and Groups VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different

effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the products of each set of Groups differ in structure, function and effect, have different modes of operation, and yield different results. Specifically, the proteins of Group IV-VI are polymers composed of amino acids which have specific inhibitory or activating activities based upon their three dimensional folded structure and act to effect the retinoic acid pathway directly. These molecules can be used for further screening assays or for enzymatic assays on protein function. The nucleic acids of Group I-III have an entirely different chemical structure, being composed of nucleotides, and operate by hybridization and by serving as a information template. Finally, the agents of Group VII and VIII are specific binding molecules which differ in structure and function from both the nucleic acids of Group II and the proteins of Group I since the agents function by specific interaction of domains to specifically interact and act upon another molecule.

3. Inventions in Groups III, VI and in Group VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, agent product of Group VII could be made by the screening methods of Groups III or VI or by chemical synthesis.

4. Inventions in Group I and in Groups II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can

be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid product of Group I can be used in the treatment method of Group II, in the screening method of Group III, in nucleic acid detection and amplification methods or in purification methods.

5. Inventions in Group IV and in Groups V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the protein product of Group I can be used in the treatment method of Group V, in the screening method of Group VI, in enzymatic assays, in protein purification assays or in antibody generation methods.

6. Inventions in Group VII and in Group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the agent of Group VII can be used in the cell growth modulation method of Group VIII, in the screening methods or in purification methods to identify counterpart molecules.

7. Inventions in Group II and in Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they differ in operation, where the Group II method operates by treating a cell or patient with a nucleic acid while the Group III method operates by mixing an agent with the nucleic acid. The inventions also differ in effect with the Group II method resulting in a treated cell or patient while the Group III method results in an identified agent.

8. Inventions in Group V and in Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they differ in operation, where the Group V method operates by treating a cell or patient with a protein while the Group VI method operates by mixing an agent with the protein The inventions also differ in effect with the Group II method resulting in a treated cell or patient while the Group III method results in an identified agent.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Also because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

10. In order to be perfectly clear, the following subgroups are NOT Subgroup elections. These are independent and distinct because each nucleic acid is structurally and functionally distinct from each other nucleic acid and molecules. The chemical structure of each polymorphism or of each different sequence differ from each other.

11. This application contains claims directed to the following patentably distinct subgroups of the claimed invention:

Subgroup I – SEQ ID NO: 1

Subgroup II – SEQ ID NO: 23

Subgroup III – SEQ ID NO: 2

Subgroup IV – SEQ ID NO: 34

Subgroup V – SEQ ID NO: 21

Subgroup VI – SEQ ID NO: 22

Subgroup VII – SEQ ID NO: 4

Subgroup VIII – SEQ ID NO: 8

Subgroup IX – SEQ ID NO: 6

Subgroup X – SEQ ID NO: 18

Subgroup XI – SEQ ID NO: 19

Subgroup XII – SEQ ID NO: 20

Subgroup XIII – SEQ ID NO: 10

Subgroup XIV – SEQ ID NO: 12

Subgroup XV –SEQ ID NO: 14

Applicant is required under 35 U.S.C. 121 to elect a single disclosed Subgroup for prosecution on the merits to which the claims shall be restricted.

Applicant is advised that a reply to this requirement must include an identification of the Subgroup that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the subgroups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the subgroups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. A telephone call was made to Mark Benedict on April 28, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jeffrey Fredman
Primary Examiner
Art Unit 1637

April 29, 2003